UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,423	01/30/2006	Arunendra Nath Lahiri Majumder	4544-051674	1726

28289 7590 09/01/2009

THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER	
PROUTY, REBECCA E	
ART UNIT	**PAPER NUMBER**
1652	

MAIL DATE	DELIVERY MODE
09/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,423	MAJUMDER ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim 2 has been canceled. Claims 1, 3-6 and newly presented claims 7 and 8 are still at issue and are present for examination.

Applicants' arguments filed on 4/23/09, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The disclosure is objected to because of the following informalities: the amino acid and nucleotide sequences of the P*orteresia coarctata* myo-inositol 1-phosphate synthase recited on page 4-5 of the substitute specification and in Figure 1 do not agree with each other. It is noted that nucleotides 67-69 of the nucleotide sequence are GAG which are shown as encoding a tryptophan (W) residue and residues 124-126 are TGG which are shown as encoding a histidine (H) residue. However, GAG is a codon for glutamic acid (E) not tryptophan and TGG is a codon for tryptophan (W) and not histidine. Thus it is not clear what the correct sequences are. Applicants should note that the sequences have not been completely checked for other errors in agreement and thus others may be present as well. The two recited instances are merely discrepancies which have been

noticed by the examiner in the course of examination. Appropriate correction is required.

Claim 2 is objected to because of the following informalities: the use of parentheses surrounding the SEQ ID NOS in claim 2 makes the claim unclear as to whether the material within the parentheses is intended as a limitation of the claims. Furthermore, the word "has" should be inserted prior to "deduced amino acid sequence". Appropriate correction is required.

Claims 1, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (upon which claims 7 and 8 depend) is indefinite and confusing in the recitation of "An isolated nucleic acid molecule for a salt tolerant L-myo-inositol 1-phosphate synthase from *Porteresia coarctata* comprising … a nucleic acid sequence having at least 70% homology to SEQ ID 1 or a nucleic acid sequence having at least 70% homology to the nucleic acid sequence encoding the protein comprising the amino acid sequence of SEQ ID NO:3" as there is only a single salt tolerant L-myo-inositol 1-phosphate synthase from *Porteresia coarctata* (i.e., SEQ ID NO:3). Thus it is unclear if it is applicants intent to

recite nucleic acids which encode variants of SEQ ID NO:3 or not. Furthermore, if nucleic acids encoding variants of SEQ ID NO:3 are encompassed it is unclear what features the nucleic acids and the encoded protein must in fact have. For purposes of further examination the "from *Porteresia coarctata*" is given no patentable weight.

Claim 1 is further confusing in the recitation of "having at least 70% homology to the nucleic acid sequence encoding the protein comprising the amino acid sequence of SEQ ID NO:3" as there are many different nucleic acids encoding the protein of SEQ ID NO:3 such that it is unclear to which the claimed nucleic acid must be homologous. Did applicants intend "encoding a protein having 70% homology to SEQ ID NO:3"?

Claims 1, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as filed does not provide support for the current recitation in claim 1 (upon which claims 7 and 8 depend) of "having at least 70% homology to SEQ ID 1 or a nucleic acid

sequence having at least 70% homology to the nucleic acid sequence encoding the protein comprising the amino acid sequence of SEQ ID NO:3". This is a new matter rejection.

Claims 1, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. For a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have

> been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the biomolecule, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed biomolecule."

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

These claims are directed to a genus of nucleic acids encoding a salt-tolerant L-myo-inositol 1-phosphate synthase said nucleic acid having at least 70% homology to SEQ ID 1 or a nucleic acid sequence having at least 70% homology to the nucleic acid sequence encoding the protein comprising the amino

acid sequence of SEQ ID NO:3". The specification teaches the structure of only a single representative species of such nucleic acids (i.e., SEQ ID NO:1). Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding a salt-tolerant L-myo-inositol 1-phosphate synthase. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding the protein of SEQ ID NO:3 and vectors and host cells comprising said nucleic acids, does not reasonably provide enablement for any nucleic acid encoding a salt-tolerant L-myo-inositol 1-phosphate synthase having 70% homology to SEQ ID NO:1 or encoding a protein having 70% homology to SEQ ID NO:3 and vectors and host cells comprising said nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1, 7 and 9 are so broad as to encompass any nucleic acid encoding a salt-tolerant L-myo-inositol 1-phosphate synthase having 70% homology to SEQ ID NO:1 or encoding a protein having 70% homology to SEQ ID NO:3. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acids broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to a single nucleic acid encoding a salt-tolerant L-myo-inositol 1-phosphate synthase (i.e., SEQ ID NO:1, which encodes SEQ ID NO:3).

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims,

and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass any nucleic acid encoding a salt-tolerant L-myo-inositol 1-phosphate synthase having 70% homology to SEQ ID NO:1 or encoding a protein having 70% homology to SEQ ID NO:3 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting L-myo-inositol 1-phosphate synthase activity; (B) the general tolerance of L-myo-inositol 1-phosphate synthase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleotide residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any nucleic acid encoding a salt-tolerant L-myo-inositol 1-phosphate synthase having 70% homology to SEQ ID NO:1 or encoding a protein having 70% homology to SEQ ID NO:3. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of nucleic acids having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 11-187879 (reference 1 of applicants IDS).

JP 11-187879 teaches a nucleic acid encoding a L-myo-inositol 1-phosphate synthase having 75% identity to SEQ ID NO:3 and vectors and bacteria comprising said nucleic acid.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raychaudhuri et al. in view of Yoshida et al. The rejection is explained in the previous Office Action.

Applicants argue that Raychaudhuri et al. and Yoshida et al. do not teach or suggest the process of obtaining cDNA, encoding a salt-tolerant L-myo-inositol 1-phosphate synthase as required by claim 3 of the invention because they does not teach or suggest the salt-tolerant L-myo-inositol 1-phosphate synthase encoded by the nucleotide sequence of SEQ ID NO: and having a

deduced amino acid sequence of SEQ ID NO:3. However, this is not persuasive because the instant claims are not to the nucleic acid isolated but to the process of obtaining this nucleic acid. No knowledge of the nucleic acid sequence encoding the protein disclosed by Raychaudhuri et al. is necessary for a skilled artisan to use the methods of Yoshida et al. with nucleic acid from *Porteresia coarctata*. Doing so will inherently result in the isolation of the nucleic acid of SEQ ID NO:1. Applicants argue that it is a discovery of applicants that the nucleic acid of the *Porteresia coarctata* salt-tolerant L-myo-inositol 1-phosphate synthase is different from that of *Oryza sativa*. However, this is not a discovery of applicants but what an ordinary skilled artisan would have expected. A skilled artisan would be aware that the nucleic acids encoding similar proteins in related species although highly homologous are virtually never identical. Thus a skilled artisan would have expected that the nucleic acid encoding the *Porteresia coarctata* salt-tolerant L-myo-inositol 1-phosphate synthase would being structurally relat4ed but not identical to the nucleic acid encoding the *Oryza sativa* L-myo-inositol 1-phosphate synthase.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is

reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on

access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652